

REMARKS

Claims 1 - 17 are presently in the subject application.

Claims 1-6, 9-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Whitcomb, U.S. Patent No. 6,011,049 ("WHITCOMB"). It is respectfully submitted that these claims are not obvious in view of WHITCOMB.

The deficiencies of WHITCOMB presented in Applicants' Response to the Office Action of January 3, 2002, are reiterated hereat. As previously discussed, WHITCOMB reveals conventional delivery systems, such as tablets, capsules, etc. (WHITCOMB, col. 4, lines 35-41; col. 5, lines 28-33). WHITCOMB does not reveal or recognize the critical considerations involved in the subject invention, namely, the relative concentrations of each drug, the dose requirement of pioglitazone vis-a-vis metformin and the comparative solubility rates and absorption rates of each drug (the subject specification, at page 3, first through fourth full paragraphs). WHITCOMB does not reveal or hint at the unitary core formulation as defined by Applicants.

One of ordinary skill in the art in viewing WHITCOMB would understand and appreciate that WHITCOMB is only revealing a conventional "combination therapy", which involves administering two or more drugs separately. Combination therapy does not involve a mixture of two or more drugs and certainly, not the core formulation as defined by Applicants.

Reference in this regard is made to WHITCOMB, at Figure 8 ("combination therapy"); Figure 11 ("combination therapy"); Figure 12 (..."Combination Therapy"); col. 1, lines 33-34 ("It has now been discovered that **combination therapy** ..." (emphasis added); col. 2, lines 6-26 ("FIG. 8 ... metformin and troglitazone **combination therapy**" ... FIG. 11

...metformin ... troglitazone ... of combination therapy ... FIG. 12 ... metformin and troglitazone ... **combination therapy** ... (emphasis added)); col. 4, lines 38-41 ("In a preferred embodiment, the sulfonylurea, biguanide, and glitazone are formulated **individually** and administered in the same manner that each is normally used clinically." (emphasis added)); col. 6, lines 6-13 ("Overview ... troglitazone/glyburide **combination therapy** ... Patients treated with **combination therapy** ... (emphasis added)); col. 6, lines 53-54 ("... A greater number of patients treated with troglitazone **combination therapy** ... (emphasis added)); col. 11, lines 2-3 ("... **combination therapy** of troglitazone and sulfonylurea appears to be safe ..." (emphasis added)); col. 11, lines 15-17 ("CONCLUSIONS Troglitazone/glyburide **combination therapy** is well tolerated ..." (emphasis added)); and col. 15, lines 21-24 ("After the initial ... period ... the remaining subjects were **dosed** with a combination of metformin and troglitazone (1000 mg metformin **BID**, 400 MG troglitazone **QD** ..." (emphasis added)).

One of ordinary skill in the art would not be led to Applicants' core formulation from a view of WHITCOMB.

The Examiner states that:

WHEREAS Whitcomb does not teach a first layer and a core covered by at least a portion of the first [layer], it is **understood** by the Examiner that in the combination of piolitazone and metformin, portions of pioglitazone would cover metformin. (emphasis added).

Firstly, a question to be asked is **from what or whom** does the Examiner obtain his understanding. The Examiner has presented not a single authority to establish that such is true. Certainly, a core, at least a portion of which is enclosed by said first layer is not disclosed or hinted at by the "combination of pioglitazone and metformin". *In re GPAC*, 57 F.3d 1573, 35

U.S.P.Q. 2d 1116, 1123 (Fed. Cir. 1995). *Ex parte Yamamoto*, 57 U.S.P.Q. 2d 1382, 1383-1384 (BPAI 2000).

Secondly, nowhere in WHITCOMB is an **actual** combination of pioglitazone and metformin described. Accordingly, in this regard, certainly the Examiner's understanding could not have come from conjecture?

A "core" is defined in "Webster's Third International Dictionary", (1993) (copy enclosed) as "the central and often fundamental part of a body, mass or construction as distinct from the enveloping part of a difference in nature or by being cut out or separated ..." A "layer" is defined in this dictionary as "a. one thickness, course or fold laid or lying over or under another ... b. stratum, bed ...". Accordingly, **arguendo** assuming that this fertile, imaginative understanding is valid, the "combination" does not form particles which are a core of metformin i.e. a central part of a body, and the pioglitazone does not form a layer "laid or lying over" a portion of a core.

One of ordinary **skill** in the art would not consider or imagine mixed particles as being a core having a layer on a portion thereof. *In re Way*, 514 F.2d 1057, 185 U.S.P.Q. 580, 584 (CCPA 1973).

It is respectfully submitted that claims 1-6, 9-17, are not obvious, under 35 U.S. (§ 103(a), to one of ordinary skill in the art in view of WHITCOMB and allowance of these claims is requested.

Claims 1-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rieveley, U.S. Patent No. 6,153,632 ("RIEVELEY"). It is respectfully submitted that these claims are not obvious in view of RIEVELEY.

The deficiencies of RIEVELEY discussed in Applicants' Response to the Office Action mailed on January 3, 2002, are reiterated hereat. Why would one of ordinary skill in the art be led to Applicants' invention as defined in claims 1-17 when RIEVELEY does not reveal or hint at a core formulation; (2) reveals only conventional delivery vehicles (RIEVELEY at col. 6, lines 41-61); (3) does not appreciate the criticality considered in Applicants' inventive core (the subject specification at page 3, first through fourth full paragraphs, especially the fourth full paragraph).

It is respectfully submitted that claims 1-17 are not rendered obvious, under 35 U.S.C. § 103(a), in view of RIEVELEY and allowance of these claims is requested.

In the event the Examiner maintains his final rejection, enclosed is a Notice of Appeal to this rejection.

The Examiner is hereby authorized to call the undersigned attorney of record "collect" on any matter connected with this application. The telephone number is 212-588-0800. In the absence of the undersigned attorney of record, the call will be accepted by any attorney empowered in this application.

Respectfully submitted,

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Webster's
Third New
International
Dictionary

UNABRIDGED

2000-01-02

[Sp — more at **CORDOBA**] 1 : cordovan leather
cordobán \kōr'dō-bān\ adj. cap [Sp *cordobán*, fr. *Córdoba*, Argentina + *-án* (as in *cordobán* of *Córdoba*, Spain)] : of or belonging to *Córdoba*, Argentina

cordón \kōr'dōn\ n, (s) (-dān) : 1 : *dimin.* of *corde* string, rope — more at **CORD** 2 : a : an ornamental cord, braid, lace, or string used esp. on costumes as (1) : an ornamental cord encircling a heraldic shield esp. of an ecclesiastical dignitary (2) : a cord or ribbon worn as a badge of honor or as a decoration of a coat of arms 3 : a knighthood — see **GRAND CORDON** 4 : **STRINGCOURT** 2 a : a line or series of troops or military posts placed at intervals and enclosing an area to prevent passage 5 : a barrier of any kind operating to close off, restrict, or control access or communication (a traffic — around the business center of a city) (protected from the mainland by a *series* of seven hills — *Horace Sutton*) c : a line or circle of persons or objects around any person or place (a *series* of *people* kept back the crowd) (a *series* of ramshackle market stalls was thrown around the circular facade to accommodate the provision merchants — *Lewis Mumford*) d : **CORDON SANTARE** 3 : an espalier trained to a single horizontal shoot or to two opposed shoots so as to form *cns* line

cordón \kōr'dōn\ n, -dān, -dān, in *sense 2* usu *d-n-s* vi **ED** — **INO** — **S** [MF *cordonner*, fr. *cordon*, n. 1] 1 : to ornament with a cordón 2 : to form a protective or restrictive cordón around (an area) : close to communication with the outside by a cordón — often used with *off* (were not allowed inside the front yard, which was *off* — by the police — *Marcia Davenport*)

cor-don-a-zo \kōr'dōn-ä-zō\ n, -s [MexSp, short for *Sp cordonazo de San Francisco*] autumnal storm, lit., lash of St. Francis (around whose birthday — Oct. 4 — such storms occur); *cordonazo* fr. *cordon* rope worn by friars (fr. *Sp*, fr. *OF* *cordon*) — *azo* (suffix denoting a blow) — more at **CORDON** 2 : a gusty hurricane wind that occurs along the west coast of Mexico when a tropical cyclone passes northward offshore

cor-don bleu \kōr'dōn'blyü\ esp in *senses 2* and *3* *n*, *n*, *n* [F, dim. of *cordon*] 1 : a *series* of small cord used to edge braid, to make tassels and fringes, or to outline the design of lace and embroidery 2 : a person eminent for his rank or merit in some field; specif.: a cook of great skill 3 also *cordón bleu* finch: any of several African waxbills (genus *Uraeginthus*) that have a clear bright blue breast and tail and *drab* back and underparts and that are often kept as cage birds

cor-don-bleu \kōr'dōn'blyü\ adj. *n*, *n* [F, dim. of *cordon*] 1 : a third or small cord used to edge braid, to make tassels and fringes, or to outline the design of lace and embroidery 2 : *cordón san-naire* *v* *kōr'dōn-säñä-ré* *n*, *n* **cordón sanitaires** also *cordons sanitaires* \ [F, lit., sanitary *cordón* (quarantine line)] : a chain of nations designed as a protection or buffer against a nation considered potentially aggressive or ideologically dangerous

CORDOTOMY

cordova *usu cap*, var. of **CORDOBA**

cor-do-van \kōr'dōvän\ adj [Sp *cordován* (now *cordobán*), Mozarabic alter. of *Sp*, *Cordovano*, fr. *Córdoba* (now *Córdoba*), Spain] 1 : a *series* of *Sp* cap : of or belonging to *Córdoba*, esp. *Córdoba*, Spain 2 : made of cordovan leather 3 : *cordón* *v* *kōr'dōn* *n* [Sp *cordobán*, fr. *cordobón*, adj.] 1 : cap : a native or resident of *Córdoba*, esp. *Córdoba*, Spain 2 a : a soft fine-grained colored leather manufactured of split horse-hides; goatskins, or pigskins b : leather tanned from the inner layer of horsehide from the rump area and distinguished by its nonporosity, density, and long-wearing qualities (called also *shell-cordovan*) 3 a : a dark grayish brown that is yellower than average chocolate brown and yellow and slightly less strong than African brown b : a variable color averaging a dark grayish brown that is darker and slightly yellower than average rosy brown

cord pl of **CORD**, pred *dim* of **CORD**

cord switch *v* : a *series* of switch mounted at the end of a cord suspended from a ceiling fixture — called also *pendant switch*

cord tire *v* : a pneumatic tire having a carcass constructed of cords running parallel to each other and crossed by small threads

cordu-lla \kōr'dü'lä\ *v* *kōr'dü'lä* *d'yü'lä*, *-(r)jä-lä* *n*, *cap* [NL, prob. *irreg.* fr. LGr *kordylé* club, fr. Gk, bump, swelling, prob. fr. the shape of the column — more at **CARDINAL**] : a large genus of tropical Old World terrestrial orchids resembling the common lady's-slipper

cor-du-roy \kōr'dü'rō\ *v* *kōr'dü'rō* *n*, *adj* sometimes: *-(r)dy*, or *-(r)ja*, *n* — *s* often attrib [earlier *corduroy*, perh. fr. the name *Corderoy*] 1 a : a cut-pile fabric of textile ribs or wales usu. made of cotton in plain or twill weave in various weights with up to 22 wales per inch; used for clothing and interior decoration (a *series* of *rows*) 2 : *corduroys* *pl* : trousers of corduroy 2 a : **CORDUROY ROAD** b : the material or structure of such a road 3 : a road surface ribbed transversely

corduroy \kōr'dü'ro\ *v* *ED* — **INO** — **S** 1 : to build (a road) of logs laid side by side transversely 2 : to build a corduroy road across (as a swamp)

corduroy road *n* : a road built of logs laid side by side transversely and usu. used in low or swampy places

cord-wain \kōr'dü,wān\ *n* — *s* [ME *cordwaine*, fr. *OF* *cordoain*, fr. *Sp* *cordován* (now *cordobán*) — more at **CORDOVAN**] : an archaic : cordovan leather

cord-waine-r \kōr'dü,wān' *n* — *s* [ME *cordewaine*, fr. *OF* *cordoainer*, fr. *cordain*] 1 : a *series* : a worker in cordovan leather 2 : show-off

cord-wain-er \kōr'dü,wān' *n* — *ES* : **SHOEMAKING**

cord-wind-er \kōr'dü,wind' *n* — *s* [by folk etymology + *WIND*]

CORDWAINER

cordwood \kōr'dü,wöod\ *n* [cord (measure) + wood] : wood piled up or sold in cords; wood for fuel cut to the length of four feet so as to be readily measurable in cords; also : standing timber of such size and quality as to be fit only for burning as fuel

cordy \kōr'dü\ *n*, *-d(s)z*, *-d(i)* *adj* **ER-EST** 1 : of or like cord : having cords or parts resembling cords 2 : of a *series* of striated appearance

cordy-ceps \kōr'dü,sëps\ *n*, *cap* [NL, *irreg.* fr. LGr *kordylé* club, fr. Gk, bump, swelling + *L*-*ceps* (fr. *caput* head) (more at **CARDINAL HEAD**) : a small family of spiny ovoviparous African lizards somewhat resembling tiny crocodiles

cordy-licious \kōr'dü'lëshës\ *n* [NL, *irreg.* fr. LGr *kordylitës* *life*, fr. *kordylitë* water net] + *-licious*: prob. akin to *cordy* *bump*, swelling — more at **CARDINAL** : a small family of spiny ovoviparous African lizards somewhat resembling tiny crocodiles

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TEST AVAILABLE COPY

lat- *adj* [ME *laxatif*, fr. ML *laxativus*, *lat-* 1 : having a tendency to loosen or relax bowel movements and relieving *lat-* 2 : subject to looseness or free bowel's b : subject to or marked by *obese* and *~ robust* —Christopher animals are liable to become too ~ running freely — *LOOSE UNRESTRAINED* *lat-* *adv* — *lax-a-*

laxatif, fr. *laxatif*, adj. 1 : a laxative

— *prob. fr. (assumed) NL *laxitudo*, *-latus* -ism* : a viewpoint in the that in a conflict between liberty

able argument for liberty suffices to — compare *PROBABILITY* 2

lb. fr. (assumed) NL *laxista*, fr. L *laxus* in *laxum*

lax- *ES* [*L* *laxitatis*, *laxitas* spaciousness, cious + *-lat-*, *-itas* -ity] 1 : the quality

1 : *LOOSENESS* (a certain ~ of bowels)

~ (in his grip) : lack of strictness (a

lack of structure or texture (a ~ in

4 : *CARELESSNESS* (a ~ in handling

etc.)

y or state of being lax

— *aid*; laying: lays [ME *leyen*, *leggen*, HG *leggen* to lay, ON *leggja*, Goth

root of OE *legian* to lie — more at

with force; beat down; strike pro-

wing; club *laid* him in the dust)

and rain) 2 : to put or flat a : placed carefully or gently (laid

shoulder) *laid* her hat on the table)

or rest; sleep; esp: *bury* c : to

in formal use d : to cause (as land)

or to seem lower and lower by

to *raise* 3 a : to produce and

set (as a mine) in the ground or in

or spread (a smoke screen) from

ut down (as in writing, in rhyme,

use to be still) — *CALM*, *ALLAY* (manu-

o waves) *H.A. Calahan* (~ the

and laid the wind) — *John Milton*;

put) to return the *lay* (the *lay* or *low*)

a *way*; *lay* also: 1 : to be on or

— *LEDGE*; *MORTGAGE* 2 : *dig* Eng : to

to press down smooth and

nap) *warp* slashing ~ the surface

it more compact, smoother, and

— *Technol.*) 9 : *LAYER* 10 a : *obs* : to

obs : to deal a blow to 11 a : *obs* : to

on (a place) b : *obs* : to quarter (as

dispose over or along a surface (~

or a prepared position) (~ a

a wire) (~ pipe to a spring) b : to

laid (~ past) 2 : to place

or wall or a rope; d : to put (strands)

a rope; *hawser*; or cable; also: to

ordage; *span*; *bind* — often

in order for a meal (~ the table)

e people) 14 a : *impost* — some

to place (new type) in a case — a

1 : to impose as a duty; burden, or

and) *his father laid* an injunction

the secret) b : *INFLECT* (~ blows)

den of reproach (found someone to

deserve punishment) c : *check* (to

door; despite; strenuous) d : *material* (material on something (~ stress

id special stress; on cleanliness)

or of details of: ~ *CONTRIVE* (when

sake, they ~ no elaborate schemes

aid plot) (must somehow form part

of the book) — *F.A. Swinnerton*)

3 : *APPLY* (*laid* the watch to his ear)

1 : to put in position for action or

fixing; *get* (a gun for grinding)

(the shirt was laid alongside the

before ~ing) 2 : to put in place (~

the gun) with the proper direction

the desired trajectory) 19 : *ANNEX*,

item that ~ ~ field to field — *Isa*

to lie in a (specified) condition (so

open with a liquor bottle — *Earl*)

4 : *employees* . . . whose behavior

— *Elmer Davis* (seem to have

in certain inhibitions — *V.L. Parrington*)

— *deration* 5 : *forward*; *ASSERT*,

or *estate* (*laid* *forward* information

item for selling liquidation)

b : to submit for examination and

the commission) 22 : to place

quarterdeck all the liberty party)

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assert strongly; *PREDICT*, *DECLARE*

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